(2) Claims 72-73, 77, 81 and 85 pending in this application remain rejected under 35 U.S.C. § 101 since the claimed invention is allegedly "not supported by either a specific and/or substantial asserted utility or a well established utility." According to the Examiner, the disclosure on page 29 of the specification "merely invites others to experiment to discover what specific disease states may be treated from a laundry list" of utilities. The Examiner specifically refers to the statement in the full passage on lines 2-8 to the effect that "GFRα3 or its agonist or antagonists can be used to treat conditions . .. " in support of the notion that one skilled in the art would not reasonably know which specific "conditions" could be treated, nor reasonably know what "agonists or antagonists" putatively exist, if later discovered. The ultimate basis for this rejection is that GFRα3 was an orphan receptor at the time the present invention was made and, in the Examiner's view, for this very reason it did not have any "real world" utility as of the filing date.

Just as before, the rejection is respectfully traversed.

The legal framework

The statutory requirement (35 U.S.C. 101) that the invention must be "useful" has been interpreted as requiring that a specific and substantial credible utility must be available as of the filing date, either as asserted in the specification or as well established in the art.

The requirement of "specific utility" means a utility specific to the claimed subject matter, as opposed to a general utility which applies to a broad or collective class of inventions. See, e.g., M.P.E.P. 2107.01 (8th ed Aug. 2001). Thus, a statement that a compound is "biologically active" or has "biological properties" is insufficient to establish patentable utility (In re Kirk, 375 F.2d 936, 941, 153 USPQ 48, 52 (C.C.P.A. 1967)). Similarly, the mere disclosure that a compound may lead to the production of future compounds is insufficient to establish patentable utility (In re Joly, 376 F.2d 906, 907-08, 153 USPQ 45, 46-47 (C.C.P.A. 1967)).

The requirement of "substantial utility" concerns a real world utility in a currently available form (Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (Fed. Cir. 1966)).

An assertion of a specific and substantial utility is considered to be credible unless the logic underlying the assertion is seriously flawed. Thus, the asserted utility is considered

credible if a person of ordinary skill in the art would accept that the invention is currently available for the use asserted by the applicant as of the effective filing date.

It is sufficient to establish one patentable utility in order to meet the utility requirement of 35 U.S.C. 101.

The claimed invention

The claims pending in this application concern nucleic acid molecules encoding the GFRα3 polypeptide of SEQ ID NO: 17, vectors comprising such nucleic acid molecules, host cells comprising such vectors, and a process directed to the recombinant production of a GFRα3 polypeptide by culturing such host cells. The common feature of all claims is the use of a nucleic acid encoding a GFRα3 polypeptide of SEQ ID NO: 17, and the question is whether applicants have established at least one patentable utility for such nucleic acid.

Utility information provided in the present application

The polypeptide of SEQ ID NO: 17 is a human GFRα3 receptor. Although nucleic acids and polypepides may have different utilities, utility of a polypeptide also establishes utility for the nucleic acid encoding such polypeptide.

The specification, in the passage bridging pages 28 and 29, provides that "[a]gents which bind to the GFRα3 molecule could be useful in the treatment of diseases or conditions involving the peripheral nervous system," such as "peripheral neuropathies associated with diabetes, HIV, chemotherapeutic agent treatments" and neuropathic pain. In the same section "antagonists" of GFRα3 are stated to be useful "to treat chronic pain of non-neuropathic nature, such as . . . that which is associated with various inflammatory states." The inventors proceed by explaining that these asserted utilities "are consistent with the data of Example 5 in which a strong expression of GFRα3 within the developing and adult sensory ganglia was observed." At page 29, lines 9-14, the inventors further note that "The surprising, relative lack of expression of GFRα3 in many organs, including notably brain, gut, and kidney indicates that the ligand (and other agonists and antagonists) which binds this receptor lacks some side effects which may be associated with ligands which bind to GFRα1 and GFRα2 (GDNF and neurturin). Thus, ligands which act via GFRα3 will be particularly useful to treat disorders of the peripheral nervous system while including fewer effects on weight loss, motor functions, or on kidney function than would ligands acting via GFRα1 or GFRα2."

According to the definition provided at page 15, lines 8-10, the term "ligand" is used to refer to a molecule which is able to bind to the extracellular α-subunit receptor of interest, or a known agonist thereof. Accordingly, the term "ligand" is not limited to the native biological ligand of a receptor. Indeed, on pages 29-33, the specification provides a detailed disclosure of anti-GFRα3 antibodies, which are clearly within the scope of "ligands" as defined for the purpose of the present invention.

Application of the law

The totality of the disclosure provided in the specification reasonably conveyed to one skilled in the art at the effective filing date of this application that agents (including antibodies) which bind to GFRα3 find utility in the treatment of neuropathies associated with the peripheral nervous system, and chronic pain, whether neuropathic or non-neuropathic in nature.

According to the Examiner, the specification discloses a "laundry list" of utilities, therefore, it merely invites one skilled in the art to discover which specific disease states should be treated. This assertion is believed to be entirely misplaced. As noted above, the disclosure of the present application consistently states the involvement of GFRα3 in peripheral neuropathies and pain. This specific disclosure, which is supported by the data disclosed in Example 5, can hardly be characterized as involving a "laundry list" of utilities, and qualifies a "specific utility" within the meaning of 35 U.S.C. § 101.

The asserted utility is also "substantial," since it provides a real world utility in a currently available form.

The asserted utility is not based in any way on the discovery of putative ligands of GFRα3 that were not known in the art at the effective filing date of the present application. In view of the teaching of the specification, the knowledge of the native ligand, or the discovery of "putative" agonists or antagonists is not required to utilize the invention for the stated purpose. Antibodies specifically binding GFRα3 could be readily generated at the filing date of this application, both based on the detailed teaching in the specification, and on general knowledge in the art. The use of such antibodies to treat the indicated conditions was well within the skill of the art at the relevant time frame. Accordingly, the stated specific utility was currently available as of the filing date, and is also "substantial."

It is emphasized that the utility should be examined in the context of the claimed invention. The claims are not directed to the identification of the native ligand, or any "putative" ligand of GFRα3, and the invention as claimed has utility without such discovery.

Finally, the logic underlying the asserted specific and substantial utility is not seriously flawed, therefore, one skilled in the art would have found the stated utility "credible" at the effective filing date of this application.

Since the claimed invention is supported by a specific and substantial asserted utility, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

All claims pending in this application are in *prima facie* condition for allowance, and an early issuance of a Notice of Allowance is respectfully solicited.

Please charge any additional fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 25, 2002 By: _____

Ginger R. Dreger
Registration No. 33,055
Attorney of Record
Customer No. 20,995
(415) 954-4114

W:\DOCS\GRD\GRD-9017.DOC
092402